K063460

DEC - 7 2006

ACUMED®, LLC

5885 N.W. Cornelius Pass Road, Hillsboro, Oregon 97124-9432 Tel (503) 627-9957

510(k) Summary

This summary regarding 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter Information: Acumed LLC
5885 N.W. Cornelius Pass Road
Hillsboro, OR 97124-9432
USA
Phone: (503) 627-9957
FAX: (503) 686-7102
Contact: Ed Boehmer, Regulatory Compliance Officer

Classification Name:	Single/multiple Component Metallic Bone Fixation Appliances and Accessories
Common Name:	Plate, Fixation, Bone
Proprietary Name:	Acumed Congruent Bone Plate System
Proposed Regulatory Class:	Class II, 21 CFR 888.3030
Device Product Code:	HRS
Legally Marketed Equivalent Device(s):	Acumed LLC Congruent Bone Plate System K012655

Device Description: The Acumed Scapula Congruent Bone Plate System consists of bone plates and screws for fractures, fusions, and osteotomies. The bone plates are pre-bent to minimize bending which is done intraoperatively. Instruments are supplied with the implants to aid in the insertion of the plates and screws. All plates and screws are manufactured from titanium in conformance with ASTM F67 and ASTM F136 and stainless steel in conformance with ASTM F138 and ASTM F2229. Plates and screws are provided non-sterile.

Intended Use: The Acumed Congruent Bone Plate System provides fixation for fractures, fusions, or osteotomies for the clavilce, humerus, radius, ulna, metacarpal, metatarsal, malleolus, tibia. and fibula.

These are similar to intended use of predicate devices and do not raise new issues of safety and effectiveness.

Technological Characteristics: The Acumed Scapula Congruent Bone Plate System is made out of Titanium as per ASTM F136 and Stainless Steel ASTM F138 and ASTM F2229. The predicates devices listed use similar materials

An assessment of performance data is not applicable.
A discussion of clinical and non-clinical tests is not applicable.

Based upon the similarities of the Acumed Congruent Bone Plate System and the predicate devices studied, the safety and effectiveness of the Acumed Congruent Bone Plate System is substantially equivalent to the predicate devices referenced.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 7 2006

Acumed, LLC
% Mr. Ed Boehmer
Regulatory Compliance Officer
5885 NW Cornelius Pass Road
Hillsboro, Oregon 97124

Re: K063460
Trade/Device Name: Acumed Congruent Bone Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: November 10, 2006
Received: November 15, 2006

Dear Mr. Boehmer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known):

Device Name: Acumed Congruent Bone Plate System

Indications For Use:

The Acumed Congruent Bone Plate System provides fixation for fractures, fusions, or osteotomies for the clavilce, humerus, radius, ulna, metacarpal, metatarsal, malleolus, tibia. and fibula.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman for MCM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063460